K080902

JUN 13 2008

510(k) Summary
(*per 21 CFR 807.92*)
Lorenz Biotech S.p.A.
FREMS™ SSC Disposable (Foam and Non-Woven) Electrodes

1. SPONSOR

Lorenz Biotech S.p.A.
Via Statale 151/A
41036 Medolla
Italy

Contact Person: Mr. Elio Cirelli
Email address: elio.cirelli@lorenzbiotech.it
Date Prepared: March 31, 2008

2. DEVICE NAME

Proprietary Name:	FREMS™ SSC Disposable (Foam and Non-Woven) Electrodes
Common/Usual Name:	Cutaneous stimulation electrodes
Classification Name:	Cutaneous electrodes

3. PREDICATE DEVICES

- NeuroEase (K831785, Andover Medical Inc.; currently shown as being manufactured and listed by Empi)
- Snap Ease (K822224, K854513, Empi; currently shown as being manufactured and listed by Empi)

4. DEVICE DESCRIPTION

The Lorenz Biotech S.p.A. FREMS™ SSC Disposable (Foam and Non-Woven) Electrodes are accessories for Lorenz Biotech Aptiva™. The silver/silver chloride conductors are covered with Apti-Gel, a medical hydrogel coupling agent. The FREMS™ SSC Disposable Electrodes are provided with either foam or non-woven backing in sealed pouches of 30 electrodes.

5. INTENDED USE

The Lorenz Biotech S.p.A. FREMS™ SSC Disposable (Foam and Non-Woven) Electrodes are accessories to the Lorenz Biotech Aptiva™ and are intended to be used for electrical stimulation. They are non-sterile and for single patient use only.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Lorenz Biotech S.p.A. FREMS™ SSC Disposable (Foam and Non-Woven) Electrodes are substantially equivalent to specified predicate devices based on intended use, indications for use, operational characteristics, fundamental technological characteristics, and performance characteristics. A detailed side-by-side comparison of the FREMS™ SSC Disposable Electrodes with cited predicate devices is included in this premarket notification.

7. PERFORMANCE TESTING

Performance testing of the FREMS™ SSC Disposable Electrodes demonstrates that they meet prospectively defined design and performance specifications. Side-by-side testing of impedance demonstrates comparable results to those obtained with the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 2008

Lorenz Biotech S.p.A
% Medical Device Consultants, Inc.
Ms. Rosina Robinson, RN, MEd, RAC
Principal Consultant, Regulatory Services
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K080902
Trade/Device Name: FREMS™ SSC Disposable (Foam and Non-Woven) Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: March 31, 2008
Received: April 2, 2008

Dear Ms. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

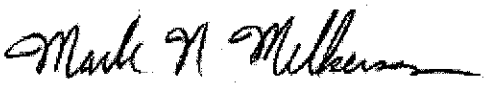
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: FREMS™ SSC Disposable (Foam and Non-Woven) Electrodes

Indications for Use:

The Lorenz Biotech S.p.A. FREMS™ SSC Disposable (Foam and Non-Woven) Electrodes are accessories to the Lorenz Biotech Aptiva™ and are intended to be used for electrical stimulation. They are non-sterile and for single patient use only.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mas

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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